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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Proposed Regulation Concerning the Use on Dietary Supplements of Health Claims Based on Authoritative Statements

Docket No. 98N-0826

Submitted On Behalf of Traco Labs, Inc.

Dear Sir/Madame:

These Comments are submitted on behalf of Traco Labs, Inc., ("Trace") of Champaign, Illinois. Traco is a manufacturer and supplier of high quality dietary supplements proving numerous health benefits.

In the Federal Register of January 21, 1999, the Food and Drug Administration ("FDA") published a proposed rule designed to formally establish a procedure for the adoption of health claims based upon authoritative statements under the notification procedures established by the Food and Drug Modernization Act of 1997 ("FDAMA"). 64 Fed. Reg. 3250-55 (Jan. 21, 1999). As noted by FDA, while FDAMA established a precise procedure for the use of these claims on behalf of conventional foods, no such procedure was set forth for dietary supplements. However, based upon the Agency's experience with the general requirements for health claims made on behalf of both conventional foods and dietary supplements, which are presented to the agency for review under identical standards and procedures, and the recommendations of Presidential Commission on Dietary Supplement Labels, FDA's proposal would apply the same procedures

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utilized for FDAMA health claims for conventional foods to claims made on behalf of dietary supplements. As noted in the January 21 Federal Register, this procedure was first set forth in the June 22, 1998 Federal Register in connection with FDA's publication of nine Interim Final Rules rejecting nine proposed FDAMA health claims submitted by Weider Nutrition International, Inc. ("the Weider Claims")

Traco applauds FDA's decision to the extent that it is based upon a determination to place conventional foods and dietary supplements on a level playing field for purposes of utilization of the FDAMA health claims procedure. This portion of FDA's proposal correctly recognizes that no rational basis could exist for creating one set of rules through which marketers of conventional foods might utilize an authoritative statement by an appropriate government agency as the basis for a FDAMA health claim while creating a different set of rules for marketers of dietary supplements.

The January 21 proposal, however, is severely flawed in its pronouncement that the Agency's "advises that the process and principles" announced in connection with its rejection of each of the Weider Claims "reflect the agency's current thinking with respect to implementation" of the FDAMA health claim procedure. 64 Fed. Reg. at 3252. FDA's determination to cling to the positions espoused in the regulations rejecting the Weider Claims is inexplicable. Since the time that the Agency first announced these "principles" in the June 22, 1998, Federal Register not only has it received numerous public comments opposing its action, but it has been advised by members of Congress that its actions flouted Congressional intent to create a streamlined procedure designed to permit health claims based upon statements of government agencies other than FDA. Moreover, the January 21 proposal appears to disregard several of the principles enunciated by the United States Court of Appeals for the District of Columbia Circuit in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir., 1998). Trace, therefore urges FDA to reevaluate its "present thinking" and to withdraw and revise the eight "Interim Final Rules" by which it rejected the Weider claims.

FDA Has Been Clearly Advised That
The Interim Final Rules Are Contrary
To The Congress Intent of FDAMA

On August 13, 1998, The Honorable Dan Burton, Chairman of the House Committee on Government Reform and Oversight, wrote to Lead Deputy Commissioner Dr. Michael Friedman to object to FDA's publication of the Interim Final Rules rejecting the Weider Claims. In that letter, Chairman Burton noted that Congress intended FDAMA Health Claims, authorized in Section 303 of that law, to:

> provide a meaningful alternative to [FDA's] overly restrictive health claims review procedure and standard . . . allowing parties to avoid that procedure and standard if they use health claims that accurately state nutrient-disease relationships published by other federal government health agencies.

Chairman Burton then went onto note that the Agency's response to the Weider Claims required "adherence to [FDA's] existing health claims procedure, defeating the very purpose of Section 303 and rendering it superfluous. "

Specifically, Chairman Burton directed Dr. Friedman's attention to the fact that Section 303 was enacted in "response to FDA's poor track record on the folic acid/neural defect claim," where FDA refused to acknowledge the validity of such a claim despite the pronouncement by the Centers For Disease Control of just such a relationship. Chairman Burton's letter also refuted FDA's claim that a passage in the Senate Report accompanying FDAMA evidenced an intent that "Section 303 would 'serve as a presumptive surrogate for FDA's deliberative review of the scientific evidence' ." Rather, Section 303, Chairman Burton noted, was designed to provide an alternative to FDA's health claim procedures and "stop FDA from preventing nutrient-disease statements published by other federal agencies from appearing in the marketplace."

Chairman Burton again addressed this issue in an October 26, 1998, letter to Commissioner Henney. At that time, he took issues with FDA's efforts to graft its own, oppressive, interpretation of an "authoritative statement" onto FDAMA, rather than utilize the straightforward requirements contained within the statute itself. As noted by Chairman Burton, FDAMA merely requires that an authoritative statement be:

1. Published by a scientific body with responsibility for public health matters (such as the Centers for Disease Control);
2. Not made by an employee of the scientific body in the individual capacity of that employee; and
3. In effect at the time the health claim is presented to FDA.

FDA's nine Interim Final Rules, however, required that an authoritative statement:

1. Represent the official policy of the scientific body;
2. Be the product of a deliberative review of the scientific evidence on the subject of the statement;

3. Not be based on preliminary or inconclusive evidence;
4. Document a valid nutrient-disease relationship that actually exists – not one that is hypothetical or merely under study; and
5. Satisfy FDA's "significant scientific agreement" standard.

Refuting FDA's claimed authority for adoption of this onerous standard, Chairman Burton's letter notes that the Agency has resorted to citation of "selective" portions of FDAMA's legislative history, whereas the legislative history as a whole clearly establishes that Congress intended "authoritative statements" to cover a much broader range of publications than contemplated by FDA.

The October 26th letter goes on to, once again, address FDA's insistence that it is within its powers to require that FDAMA health claims satisfy the "significant scientific agreement" standard. This position, Chairman Burton argues "guts Section 303 of meaning" and flouts Congressional intent to provide "as meaningful alternative" to the existing regulatory scheme. Moreover, he notes that the Senate Report Cited by FDA in the nine Interim Final Rules sets forth only one example where this standard would be applicable to FDAMA health claims – and that is where FDA specifically adopts, or has already adopted, a health claim concerning a disease-nutrient relationship. No other circumstances justifying the application of this onerous standard are mentioned in the Senate Report, or anywhere else in FDAMA or its legislative history.

Traco Labs agrees with each of the points made by Chairman Burton. FDA's nine Interim Final Rules are indisputably an effort to circumvent the Congressional intent to create an alternative to the existing, onerous, method for establishing FDA authorized health claims. In establishing the standards set forth in the Interim Final Rules, FDA has eviscerated the provisions of FDAMA which were designed to provide an alternative means for the transmission of vital health related information to the American public. Adoption of Final Regulations applying the "significant scientific agreement" standard and the Agency's revisionist definition of "authoritative statement" to FDAMA health claims would be arbitrary and capricious, and contrary to law. Such action would negate any positive effect that Section 303 might have on broadening the scope of important health information available to the American public. Moreover, FDA's obdurate insistence on application of this onerous standard will leave the door open for a repetition of the fiasco surrounding the Agency's refusal to adopt a folic acid-neural tube defect acid health claim, despite repeated statements by The Centers For Disease Control of the crucial need to increase folic acid intake in order to reduce the incidence of birth defects. The agency's statement in the January 21 Federal Register that it continues to standby its pronouncements in the nine Interim

Final Rules is ill-advised. FDA should withdraw both that comment and the nine final rules for revision consisted with FDAMA and Congressional intent.

The Decision of the Circuit Court In Pearson v. Shalala Requires FDA To Withdraw And Reconsider Its Rejection Of The Weider Health Claims

On January 15, 1998, in Pearson v. Shalala, 164 F.3d 650, the United States Court of Appeals for the District of Columbia ruled that FDA's failure to provide any definition of "significant scientific agreement" and blanket refusal to consider "qualified" health claims in rejecting four health claims submitted to it by dietary supplement marketers in 1993, failed to pass muster under both the First Amendment to the United States Constitution and the Administrative Procedure Act. The ruling in that case is directly applicable to FDA's rejection of the Weider Health Claims, and requires FDA to withdraw its rejection of those claims for revision consisted with the Pearson decision.

As part of the nine Interim Final Rules published in the June 22, 1998, Federal Register, FDA set forth its view of the appropriate standards under which FDAMA authoritative statement health claims may be made. As part of this discussion in the interim final rule rejecting proposed claims concerning the role of antioxidant vitamins C and E and the risk in adults of atherosclerosis, coronary heart disease, certain cancers and cataracts, the Agency stated that:

> "Even if a statement meets the criteria to be an "authoritative statement," Congress also provided under new Section 403(r)(3)(D)(i) of the act that FDA have the authority to prohibit a health claim based upon an authoritative statement when there is not significant scientific agreement that there is a relationship between the nutrient and the disease or health-related condition in question. "

63 Fed, Reg. at 34086. For many of the reasons discussed in Chairman Burton's letters to FDA, Traco believes that this portion of the Interim Final Rules constitutes an improper effort by the agency to abrogate unto itself the power to be the final arbiter of what health information maybe presented to the American public. This statement should be withdrawn. However, even if FDA were to continue to attempt to apply the significant scientific agreement standard to FDAMA

health claims, the Pearson decision requires that, at a minimum, the Agency provide some guidance as to what "significant scientific agreement" means.

In its decision, dated January 15, 1999, the D.C. Circuit, while declining to require FDA to revise the initial regulations setting forth the standards under which it would approve health claims, See 21 C.F.R. § 101.70, found the agency's failure to articulate just what is meant by "significant scientific agreement" either within that regulation, or within the regulations at issue in Pearson, to be a violation of the Administrative Procedures Act ("APA"), 5 U.S.C. § 553. Pearson, 164 F. 3d at 660. In reaching this conclusion, the Circuit Court specifically rejected FDA's claim that it may rely upon the "I know it when I see it" approach utilized by Justice Stewart when he declined to provide a precise definition of obscenity. Id. Rather, the D.C. Circuit held that "on remand, FDA must explain what it means by significant scientific agreement or, at a minimum, what it does not mean." 164 F. 3d at 661. Traco respectfully submits that this portion of the Pearson decision makes it incumbent upon FDA to, at a minimum, address exactly what it meant by "significant scientific agreement" at the time it promulgates final regulations in response to the Weider Claims.

Traco further believes that the remainder of the Pearson decision requires FDA to adopt a substantially more expansive definition of "significant scientific agreement" than it has previously utilized. As the Circuit Court's decision recognized, to date, FDA has uniformly rejected proposed health claims which are based on preliminary or ongoing scientific research, accompanied by any sort of limiting disclaimer or otherwise qualified in any way. See, 164 F. 3d at 653. The primary reason set forth by FDA for this approach has been its view that any claim that did not meet its definition of "significant scientific agreement" was necessarily misleading. The Pearson Court, however, found that this approach fails to pass constitutional muster under the First Amendment, as it violates the notion of Commercial Free Speech. Indeed, the Court noted that:

> As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. See *Peel*, 496 *U.S. at 105* (rejecting paternalistic assumption that the recipients of a letterhead are "no more

> discriminating than the audience for children's television"). We reject it.

164 F. 3d at *655*.

FDA has also consistently rejected the notion that truthful, non misleading health claims may be qualified in order to inform consumers of the preliminary nature of the scientific research supporting the health information they seek to convey. In support of this position, the Agency has argued that "there would be a question as to whether consumers would be able to ascertain which claims were preliminary [and accompanied by a disclaimer] and those which were not." Id. In FDA's analysis the use of disclaimers, would therefore render any health claim accompanied by any limiting disclaimer inherently "misleading." 164 F. 3d at 655. The Pearson Court also rejected this notion, stating:

> The government disputes that consumers would be able to comprehend appellants' proposed health claims in conjunction with the disclaimers we have suggested--this mix of information would, in [**30] the government's view, create confusion among consumers. But all the government offers in support is the FDA's pronouncement that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability." 59 *Fed. Reg. at 405*. Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech--here the FDA's conclusory assertion falls far short.

164 F. 3d at 659.

Traco respectful] y submits that this portion of the Pearson decision requires FDA to reconsider its rejection of the proposed Weider claims concerning 0mega3 fatty Acids and the Risk in Adults of Cardiovascular Disease, 63 Fed. Reg. 34107, and Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts, 63 Fed. Reg. 34084. While FDA rejected both of these claims primarily on the grounds that the Agency did not believe they satisfied its improperly heightened standard for authoritative statements, it also noted that each was based on statements suggesting that "more research was needed" (Antioxidant Vitamins and the reduced risk of cancer, 63 Fed. Reg. at 34089) or "that the

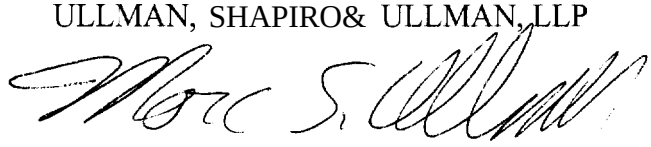
relationship is preliminary or inconclusive" (Omega3 Fatty Acids and Cardiovascular Disease, 63 Fed. Reg. at 34108). The Pearson decision clearly rejects the notion that FDA may automatically reject qualified health claims such as these on the theory that they are inherently misleading. Rather, the Pearson Court correctly recognized that if the Agency harbors legitimate concerns over potential consumer confusion, it must "meet its burden justifying a restriction on free speech – here the FDA's conclusory assertion falls far short." 164 F.3d at 659. The same holds true for the Agency's conclusory assertions contained in its rejection of the proffered claims for 0mega3 Fatty Acids and Antioxidant Vitamins.

Conclusion

Due to its failure to comport with the Congressional intent to create a viable alternative for the transmission of important, truthful and non misleading health information through the creation of FDAMA's "authoritative statement" basis for health claims, and in order to comply with the decision of the D.C. Circuit in Pearson, FDA must withdraw and revise the nine Interim Final Rules rejecting the Weider Claims. The Agency's obdurate instance in the January 21, 1999, Federal Register that its interpretation of its authority under the United States Constitution and FDAMA is correct despite the clear expressions to the contrary of Chairman Burton and the Pearson Court, is yet another unfortunate indication of the Agency's efforts to usurp for itself the role of sole arbiter of what health information maybe conveyed to the American public. Sadly, these circumstances compel Traco to agree with Chairman Burton's observation in his August 13, 1998, letter to Dr. Friedman, when he stated that FDA's position "only reinforce(s) the existing censorship effected by the [significant] scientific agreement standard. I fully expect that FDA's denial of vital health information to the public will pose a continued threat to the health of the American public."

Respectfully Submitted,

ULLMAN, SHAPIRO& ULLMAN, LLP



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